North Carolina State Opioid Treatment Authority (SOTA)
Mission, Purpose, and Role

Mission
North Carolina SOTA’s mission is to reduce the impact of opioid use disorder, in North Carolina communities and promote excellence in Opioid Treatment Programs.

Purpose
To approve, support, and monitor Opioid Treatment Programs in North Carolina and serve as a centralized point to provide collaboration between North Carolina Opioid Treatment Programs, SAMHSA, and other regulatory bodies. The North Carolina State Opioid Treatment Authority develops, monitors, and implements best practice standards and provides support for all stakeholders to promote excellence in treatment for the communities and persons served. North Carolina Opioid Treatment Programs will lead the field in providing quality care.

Scope
42 CFR, 8.11
(c) Action on application.

(1) Following SAMHSA’s receipt of an application for certification of an OTP, and after consultation with the appropriate State authority regarding the qualifications of the applicant, SAMHSA may grant the application for certification, or renew an existing certification, if SAMHSA determines that the OTP has satisfied the requirements for certification or renewal of certification.

10A NCAC 27G .3604 OPERATIONS
(d) Compliance with State Authority Regulations. Each facility shall be approved by the North Carolina State Authority for Opioid Treatment, DMH/DD/SAS, which is the person designated by the Secretary of Health and Human Services to exercise the responsibility and authority within the state for governing the treatment of addiction with an opioid drug, including program approval, for monitoring compliance with the regulations related to scope, staff, and operations, and for monitoring compliance with Section 1923 of P.L. 102-321. The referenced material may be obtained from the Substance Abuse Services Section of DMH/DD/SAS.

(e) The State Authority shall base program approval on the following criteria:

(1) compliance with all state and federal law and regulations;
(2) compliance with all applicable standards of practice;
(3) program structure for successful service delivery; and
(4) impact on the delivery of opioid treatment services in the applicable population.

Role of the State Opioid Treatment Authority

Historical Overview
1. In the 1970’s, the Federal Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA) jointly promulgated standards for methadone programs. These standards were developed to provide a means to regulate the safety and improve the effectiveness of methadone programs through formal

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1 Association of State Alcohol and Drug Abuse Directors (NASADAD)
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Approval and Disapproval of Programs
1. SOTAs must collaborate closely with federal agencies to approve and monitor OTPs within their states.
2. In general, the SOTA is responsible for ensuring that mechanisms are developed and implemented at the state level that facilitate:
   a. Approval and disapproval of treatment programs.
   b. Clarifying and supporting providers’ ability to comply with federal and state requirements related to establishing, relocating and closing treatment programs.
   c. Orderly transfer of patients, records and assets when programs are closed.
3. Federal regulations mandate that OTPs are certified by SAMHSA and registered with the DEA before beginning operations.
4. Treatment programs are also required to meet licensing and other relevant state requirements.
5. SOTAs are responsible for ensuring that treatment programs register with the DEA and the state drug regulatory agency.
6. SOTAs may facilitate the treatment programs’ completion of the FDA application and state licensing application.

Program Monitoring
1. Both the DEA and SAMHSA monitor and conduct periodic inspections of OTPs. During these inspections, they determine if the program is complying with federal regulations and operating properly.
2. State Authorities are responsible for assessing programs and determining whether they are meeting appropriate levels of quality and security in service delivery, and may be responsible for ensuring that federal and state funds are being used properly.
3. SOTAs must establish and communicate specific regulations for treatment program monitoring. These regulations must be at least as restrictive as the federal regulations and may be tailored to address special location issues such as multiple enrollment and diversion.
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4. SOTAs are responsible for identifying and communicating the consequences that will be levied against treatment programs if they do not comply with federal, state and other treatment related regulations.

5. SOTAs are required to review and approve requests for take home bottles.

Quality of Care
1. SOTAs are responsible for requiring treatment programs to develop and implement continuous quality improvement plans that include performance outcome measures.

2. SOTAs should encourage treatment programs to provide opportunities for staff training and development.

3. SOTAs are required to collect treatment program data about patient needs, services, costs and outcomes that will be used for monitoring purposes and to document the cost effectiveness of treatment.

Patient Assessment, Placement, and Treatment Planning
1. SOTAs are responsible for establishing and communicating eligibility criteria for admission to opioid treatment programs that are consistent with relevant federal regulations.

2. State Authorities should ensure that programs use intake screening processes that collect information that is sufficient for determining patients’ eligibility and suitability for treatment.

3. State Authorities are responsible for making sure that all treatment patients are oriented to their programs as soon as possible after admission, including patient education and evaluation.

4. SOTAs should ensure that treatment programs conduct comprehensive patient assessments that address placement criteria required by the federal and state regulations.

5. State Authorities are responsible for programs participating in ongoing treatment planning processes that are patient focused and appropriate for current and future treatment conditions.

6. SOTAs should ensure that programs conduct drug testing at appropriate times and administer pregnancy tests when indicated.

Program Staffing, Services, and Operations
1. SOTAs are responsible for determining and ensuring minimum levels of staffing and services required for effective opioid treatment.

2. State Authorities should ensure that the frequency and duration of counseling services meet individual patient needs and are consistent with the person’s treatment plan.

3. State Authorities are responsible for determining program hours of operation and ensuring those hours are appropriate for the patient population.

4. The SOTA is responsible for approving methadone “take-home” requests that do not comply with the federal regulations, are considered “exceptions” to those regulations and are submitted through the electronic “Extranet” system for federal and state approval.
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Ethics
1. State Authorities should adopt and communicate standards of ethical practices for counselors and other treatment program staff.
2. SOTAs are responsible for adopting the federal confidentiality regulations, HIPPA, or developing legislation that is more specific.
3. SOTAs should ensure that treatment programs adhere to patients’ rights requirements including reporting of grievances and abuse, privacy and confidentiality, and informed consent.

Working with Providers
1. The SOTA is responsible for working effectively with the opioid treatment program providers in their state.
2. It is important to develop and maintain relationships with providers that support their ability to deliver quality services to all patients, as well as ensure compliance to relevant federal and state regulations.
3. The SOTA relationship with and/or authority over providers may depend on their type, i.e., funded, non-funded, public and private.
4. States must take lead role in establishing policies, guidelines, regulations, and procedures that govern the relocation and/or closure of opioid treatment programs, and ensure continuity of care for patients.
5. The State Authority is responsible for ensuring that the state, SAMHSA, DEA, patients, and other relevant agencies are notified of the closure or relocation of treatment programs.

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